42. (New) The composition of claim 4, wherein said pharmaceutically active agent is human insulin-like growth factor 1 (IGF-I) or a biologically active variant thereof, wherein said variant is a polypeptide having IGF-I activity and at least 70% sequence identity to human IGF-I.

43. (New) The composition of claim 5, wherein said pharmaceutically active agent is human insulin-like growth factor 1 (IGF-I) or a biologically active variant thereof, wherein said variant is a polypeptide having IGF-I activity and at least 70% sequence identity to human IGF-I.--

44. (New) The composition of claim 40, wherein said pharmaceutically active agent is human insulin-like growth factor 1 (IGF-I) or a biologically active variant thereof, wherein said variant is polypeptide having IGF-I activity and at least 70% sequence identity to human IGF-I.--

REMARKS

Claims 1, 3-5, and 12 have been amended as described below. New claims 35-44 have been added. No new matter has been added by way of claim amendment or presentation of new claims.

Specifically, claims 1, 3-5, and 12 have been amended to delete the term "about" and to expand the concentration range of succinate in the composition. Amended claim 1 now recites a succinate concentration range of 7 mM to 45 mM. Support for this amendment can be found in the specification, for example on page 7, line 17, continuing through page 8, line 2. New claims 35-40 depend indirectly or directly from claim 1, and recite various ranges of succinate concentration falling within the range of 7 mM to 45 mM. New claims 41-44 are drawn to a specific embodiment of the respective base claim, where the pharmaceutically active agent is human IGF-I, or biologically active variant thereof having at least 70% sequence identity to human IGF-I. Support for these new claims can be found in the original claims and throughout the specification, for example on page 7, line 17, continuing through page 8, line 2, where various concentrations of succinate are disclosed, and on page 8, lines 20-22, where one embodiment describes human IGF-I as the pharmaceutically active agent.

Claims 1-14 and 21-44 are now pending in the application. Applicants acknowledge the Examiner's indication that claims 21-34 are allowed. The amendments presented herein were not made earlier because Applicants earnestly believed the claims were patentable as originally drafted; the present amendments are submitted to further prosecution or to reduce issues on appeal. The Examiner is respectfully requested to enter these claim amendments into the application.

The Examiner's comments in the Office Action are addressed below in the order set forth therein.

The Rejections of the Claims Under 35 USC §102(b) Should Be Withdrawn

Claims 1-3, 6-10, and 13-14 stand rejected under 35 USC §102(b) as anticipated by Bontempo *et al.* (EP 0284249). Claims 1-8, and 13-14 stand rejected under 35 USC §102(b) as anticipated by Hwang-Felgner *et al.* (U.S. Patent No. 5,151,265). Claims 1-3 and 13 stand rejected under 35 USC §102(b) as anticipated by Olefsky *et al.* (WO 96/40894). These rejections are respectfully traversed.

As previously made of record, Bontempo *et al.* disclose a pharmaceutically active agent in a 50 mM succinate buffer, Hwang-Felgner *et al.* disclose gamma-interferon in a 6.8 mM succinate buffer, and Olefsky *et al.* disclose protein kinase C antagonist in a 50 mM succinate buffer. The rejected claims recited sterile injectable pharmaceutical compositions comprising a pharmaceutically active agent and a buffer, where the buffer consisted substantially of a counterion and succinate at a concentration of "about 10 mM to about 40 mM," "about 10 mM to about 30 mM," "about 10 mM to about 20 mM," and "about 10 mM." The Examiner has reasoned that the term "about" renders these claims anticipated by the cited references, as the specification fails to define the range for the term "about." Applicants respectfully disagree for the reasons already made of record.

Solely for the purpose of furthering prosecution, the rejected claims have been amended to delete the term "about" as it pertains to the lower and upper boundaries of the succinate concentration range recited in the rejected claims. At the same time, Applicants have taken appropriate measures to protect their invention by broadening the lower and upper boundaries of

the succinate concentration range set forth in claim 1. This claim has been amended to recite a succinate concentration of 7 mM at the lower boundary of the range and a succinate concentration of 45 mM at the upper boundary of the range. This claimed concentration range is not taught or suggested by the cited prior art, nor does the cited prior art teach or suggest the benefits of this claimed concentration range.

The foregoing claim amendment has been made to address what amounts to an indefiniteness issue that has been raised by the Examiner, who interprets the term "about" to be ambiguous in the context of a range of numerical values in the absence of a clear and concise definition in Applicants' specification. Accordingly, this claim amendment has not been made to avoid the prior art cited in the Office Action. In fact, as noted above, the current amendment broadens the claim. Applicants have not surrendered subject matter by way of presentation of this claim amendment, and therefore should not be estopped from challenging equivalents of this amended claim element.

Applicants respectfully submit that independent claim 1 and its respective dependent claims 2-14 and 35-44 do not recite succinate concentrations that are anticipated by the teachings of Bontempo *et al.*, Hwang-Felgner *et al.*, or Olefsky *et al.* Therefore, the rejections of the claims under 35 USC §102(b) should be withdrawn and should not be applied to newly added claims 35-44.

CONCLUSION

In view of the above amendments and remarks, Applicants submit that the rejections of the claims under 35 USC §102(b) are overcome. Applicants respectfully submit that this application is now in condition for allowance. Early notice to this effect is solicited.
If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject Application, the Examiner is invited to call the undersigned.

It is not believed that extensions of time or fees for net addition of claims are required beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required

therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: **BOX AF**, Commissioner for Patents, Washington, DC 20231 on February 12, 2003.

Lynda-Jo Pixley

Lynda-Jo Pixley

Version with Markings to Show Changes Made:

In the Claims:

1. (Thrice amended) A sterile injectable pharmaceutical composition comprising a pharmaceutically active agent and a buffer, wherein said buffer consists substantially of succinate at a concentration of [about 10]7 mM to [about 40]45 mM and a counterion.

3. (Twice amended) The composition of claim 1, wherein the concentration of succinate is [about]10 mM to[about]30 mM.

4. (Twice amended) The composition of claim 3, wherein the concentration of succinate is [about]10 mM to [about]20 mM.

5. (Twice amended) The composition of claim 4, wherein the concentration of succinate is [about]10 mM.

12. (Twice amended) The pharmaceutical composition of claim 11, wherein the pH of said composition is about 6.0, the concentration of said succinate is [about]10 mM, and the composition further comprises about 140 mM sodium chloride.